

Bruce A. Rosenzweig

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., :Master File No.
PELVIC REPAIR SYSTEM :2:12-MD-0237
PRODUCTS LIABILITY :
LITIGATION :MDL No. 2327

THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

Mullins, et al. V.	2:12-cv-02952
Ethicon, Inc., et al.	
Sprout, et al. V.	2:12-cv-07924
Ethicon, Inc., et al.	
Iquinto v. Ethicon,	2:12-cv-09765
Inc., et al.	
Daniel, et al. V.	2:13-cv-02565
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Dillon, et al. V.	2:13-cv-02919
Ethicon, Inc., et al.	
Webb, et al. V.	2:13-cv-04517
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Martinez v. Ethicon,	2:13-cv-04730
Inc., et al.	
McIntyre, et al. V.	2:13-cv-07283
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Oxley v. Ethicon,	2:13-cv-10150
Inc., et al.	
Atkins, et al. V.	2:13-cv-11022
Ethicon, Inc., et al.	
Garcia v. Ethicon,	2:13-cv-14355
Inc., et al.	
Lowe v. Ethicon,	2:13-cv-14718
Inc., et al.	
Dameron, et al. V.	2:13-cv-14799
Ethicon, Inc., et al.	
Vanbuskirk, et al. V.	2:13-cv-16183
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SEPTEMBER 22, 2015
BRUCE A. ROSENZWEIG, M.D.

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2	Mullens, et al. V.	2:13-cv-16564
3	Ethicon, Inc., et al.	
	Shears, et al. V.	2:13-cv-17012
4	Ethicon, Inc., et al.	
	Javins, et al. V.	2:13-cv-18479
5	Ethicon, Inc., et al.	
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6	Ethicon, Inc., et al.	
	Lambert v. Ethicon,	2:13-cv-24393
7	Inc., et al.	
	Cook v. Ethicon, Inc.	2:13-cv-29260
8	Stevens v. Ethicon,	2:13-cv-29918
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9	Harmon v. Ethicon, Inc.	2:13-cv-31818
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10	Inc., et al.	
	Miller v. Ethicon, Inc.	2:13-cv-32627
11	Matney, et al. V.	2:14-cv-09195
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12	Jones, et al. V.	2:14-cv-09517
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13	Humbert v. Ethicon,	2:14-cv-10640
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14	Gillum, et al. V.	2:14-cv-12756
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15	Whisner, et al. V.	2:14-cv-13023
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16	Tomblin v. Ethicon,	2:14-cv-14664
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17	Schepleng v. Ethicon,	2:14-cv-16061
	Inc., et al.	
18	Tyler, et al. V.	2:14-cv-19110
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19	Kelly, et al. V.	2:14-cv-22079
	Ethicon, Inc., et al.	
20	Lundell v. Ethicon,	2:14-cv-24911
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21	Cheshire, et al. V.	2:14-cv-24999
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22	Burgoyne, et al., V.	2:14-cv-28620
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23	Bennett, et al., V.	2:14-cv-29624
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The deposition of BRUCE A. ROSENZWEIG,
M.D., called for examination, taken pursuant
to the Federal Rules of Civil Procedure of the
United States District Courts pertaining to the
taking of depositions, taken before JULIANA F.
ZAJICEK, CSR No. 84-2604, a Certified Shorthand
Reporter of said State of Illinois, at the offices
of Wexler Wallace LLP, Suite 3300, 55 West Monroe
Street, Chicago, Illinois, on September 22, 2015,
at 10:05 a.m.

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1 (WHEREUPON, the witness was duly
2 sworn.)

3 BRUCE A. ROSENZWEIG, M.D.,
4 called as a witness herein, having been first duly
5 sworn, was examined and testified as follows:

6 EXAMINATION

7 BY MR. SNELL:

8 Q. Good morning, Dr. Rosenzweig. How are you
9 doing?

10 A. Good morning, sir. Just fine. Thank you.

11 Q. I'm here to take your deposition in the
12 Mullins case which is a multi-plaintiff case currently
13 pending in the Ethicon MDL.

14 You are aware of that, right, Doctor?

15 A. Yes.

16 (WHEREUPON, a certain document was
17 marked Rosenzweig Deposition Exhibit
18 No. 1, for identification, as of
19 09/22/2015.)

20 BY MR. SNELL:

21 Q. And I've handed you Exhibit No. 1 which I
22 will represent to be your Notice of Deposition.

23 Have you seen this document before, sir?

24 A. Yes, I have.

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1 **Q.** Okay. So which one were you talking
2 about?

3 **A.** I was talking about the an Lynette study,
4 but if you want to talk about the Okulu study, yes,
5 that was Ultrapro versus GYNEMESH PS for a sling and
6 there were fewer erosions in the -- with the sling
7 made of Ultrapro.

8 **Q.** So the study you were referencing was
9 which one?

10 **A.** It's the Lynette, part of the Milani
11 papers.

12 **Q.** Is that identified in your report?

13 **A.** Is that on this reliance list? No, not
14 that I'm aware of.

15 **Q.** The Okulu study which is the one that I
16 thought you were talking about, that's the one that
17 looked at Vypro, Ultrapro and Prolene Soft, right?

18 **A.** Right, and you and I have had a discussion
19 about why Vypro has significant --

20 **Q.** So I don't have to ask you that again.

21 **A.** Excellent.

22 **Q.** But we can agree that in Okulu they did
23 not use the TVT retropubic device, correct?

24 **A.** That is correct.

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1 **Q.** They didn't use sheaths, correct?

2 **A.** That is correct.

3 **Q.** They didn't place it tension-free,
4 correct?

5 **A.** If you have the Okulu study, I'd -- to
6 look at, I can answer that question about tension.

7 **Q.** Do you recall they tied the sutures off up
8 top in the Okulu study in the way that they performed
9 that placement?

10 **A.** Just by tying the sutures that doesn't
11 mean that it was placed under tension.

12 **Q.** Let's give him the study just so we are
13 clear.

14 (WHEREUPON, a certain document was
15 marked Rosenzweig Deposition Exhibit
16 No. 4, for identification, as of
17 09/22/2015.)

18 BY MR. SNELL:

19 **Q.** So on page 219 of Exhibit 4, the Okulu
20 study, they report on their operative technique,
21 correct?

22 **A.** That is correct.

23 **Q.** And there are a lot of differences between
24 that technique and the TVT retropubic technique,

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1 correct?

2 **A.** That is correct, but it does not say that
3 they placed it under tension.

4 **Q.** Including, let's see, they made an
5 A-shaped incision -- inverted A-shaped incision to the
6 interior vaginal wall, correct?

7 **A.** That is correct.

8 **Q.** You don't do that with the TVT, correct?

9 **A.** That is correct.

10 **Q.** And then they made some patch that was 3
11 by 4 centimeters in most patients, correct?

12 **A.** That is correct.

13 **Q.** And that is not done with the TVT,
14 correct?

15 **A.** That is correct.

16 **Q.** And if we look down, it talks about all of
17 the different tools and Kishner needles, prolene
18 sutures that were used, correct?

19 **A.** Yes.

20 **Q.** What are Kishner needles and how do they
21 compare to Stamey needles that I've heard of?

22 **A.** I have not used a Kishner needle, but I
23 would assume that it was similar to a Stamey needle.

24 **Q.** It says, "After confirmation that the

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1 bladder and urethra were normal, the prolene sutures
2 were ligated crosswise in the suprapubic region,"
3 correct?

4 A. That is correct.

5 Q. What does that mean?

6 A. That the sutures were tied to one another.

7 Q. Up top in the -- above the rectus fascia?

8 A. That is correct.

9 Q. "Special attention was paid not to create
10 much tension on the mesh material."

11 Do you see that?

12 A. That is correct.

13 Q. Do you know what methodology they would
14 have used to not create much tension on the mesh
15 material when they utilized the tying off of the
16 prolene sutures?

17 A. It was probably the similar methodology
18 used to avoid tension with the TVT.

19 Q. Dr. Blaivas testified that when he does
20 his autologous slings, he'll put a single finger
21 breadth and tie the sutures over top.

22 Do you recall seeing that?

23 A. Yes.

24 Q. Is that how -- withdrawn. I think you and

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1 **A.** We can go to page 4 and 5 where in general
2 my expert opinions can be summarized as following.

3 **Q.** So we have numbered paragraphs with
4 letters A, B, C, D, E, F on page 4, carrying over G,
5 H, I, J page 5, correct?

6 **A.** That is correct.

7 **Q.** And that's a summary of your opinions?

8 **A.** That is correct.

9 **Q.** In your opinion should Ethicon's TVT
10 retropubic device be significantly changed or modified
11 in its design?

12 MR. CARTMELL: Object to the form.

13 BY MR. SNELL:

14 **Q.** And if you have such an opinion, tell me
15 how it should be changed?

16 **A.** The use of a -- and we are talking about
17 an embodiment of something that is currently available
18 on the market, right?

19 **Q.** No.

20 **A.** So the design should be a device that uses
21 a partially absorbable mesh with -- such as Ultrapro
22 which has been shown to have less stiffness, large
23 enough pore size, light enough weight to decrease the
24 risk of the -- long-term risks of the procedure to a

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1 level where the risk/benefit analysis is not
2 significantly skewed to the risk.

3 Q. How many studies are there that you are
4 aware of that analyzed the TVT retropubic device with
5 the meshes currently in it?

6 A. How many studies are there?

7 Q. Yes, sir.

8 A. There are a lot.

9 Q. How many randomized control trials are
10 there for the TVT retropubic device using the prolene
11 polypropylene mesh?

12 A. High quality, long term?

13 Q. No, no, altogether.

14 A. Altogether, over 100.

15 Q. Okay. And now, so how many of those TVT
16 retropubic device randomized control trials do you
17 believe are high quality?

18 A. If you look at the assessment of the
19 literature that's out there, the majority are of a
20 moderate quality to low quality. They are short-term
21 studies. They have a low number of subjects in each
22 of the groups. They are looking mostly at efficacy.
23 Safety is not a primary endpoint for any of the
24 long-term studies that I have seen. They are all

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1 believed that the design of TVT should have used a
2 partially absorbable mesh like Ultrapro, correct?

3 A. That's an embodiment, yes.

4 Q. And what clinical studies in women for the
5 application of stress incontinence, if any, are you
6 relying on for that statement?

7 A. We have the Okulu study which used
8 Ultrapro and showed to have a higher success rate,
9 lower complication rate, than a stiffer, smaller pore,
10 heavier weight mesh. You -- the -- work from the
11 Moalli group, there were multiple studies on mesh
12 stiffness showing the complications associated with a
13 stiffer mesh. There are more complications associated
14 with a heavier weight mesh. There are more
15 complications associated with a smaller pore mesh.
16 So, if you design a mesh that is lighter weight,
17 larger pore, less stiff, smaller filament size, you
18 will have fewer complications and have a better
19 risk/benefit ratio.

20 Q. How many randomized control trials are you
21 aware of that have evaluated Ultrapro and the intended
22 use of stress urinary incontinence?

23 A. There is the Okulu study.

24 Q. So one study?

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1 **A.** That is correct.

2 **Q.** And that's the Okulu study we discussed
3 earlier today?

4 **A.** That is correct.

5 **Q.** That was in 2003?

6 **A.** Yes.

7 **Q.** So for your statement that the lighter
8 weight, larger pore mesh should have been used, you
9 can cite to a single clinical study in women with the
10 application of stress urinary incontinence, the Okulu
11 study?

12 MR. CARTMELL: Object to the form.

13 BY THE WITNESS:

14 **A.** Well, there are other studies showing the
15 why you would move to a -- in a pelvic floor
16 application to a larger pore, lighter weight, smaller
17 filament, less stiff mesh.

18 BY MR. SNELL:

19 **Q.** But the larger pore, lighter weight, less
20 stiff theory that you are talking about has only been
21 tested in one study you can point me to for the
22 application of stress urinary incontinence?

23 MR. CARTMELL: Object to the form.

24 BY MR. SNELL:

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1 **Q.** Correct?

2 **A.** Specifically for stress urinary
3 incontinence, yes, but for -- but to show why that is,
4 there are multiple studies that show why it's
5 advantageous in the pelvic floor to have a larger
6 pore, lighter weight, less stiff mesh because of
7 processes that lead to cell death, that lead to smooth
8 muscle dysfunction, that lead to more erosions, that
9 lead to more complications.

10 **Q.** The Moalli papers you are referring to are
11 not in women who received Ultrapro and who received
12 Ultrapro for stress urinary incontinence and were
13 followed over one or more years, correct?

14 **A.** The multiple studies by the Moalli group
15 that looks at the stiffness of mesh and the
16 consequence of stiffness of mesh are in an animal
17 model. There is basic science research that shows the
18 difference between the stiffness of mesh. There are
19 multiple other clinical studies that show the decrease
20 in complications associated with a lighter weight,
21 larger pore mesh compared to a medium weight, smaller
22 pore mesh.

23 **Q.** And just so I'm clear, all of the Moalli
24 papers you cited are animal model papers?

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1 **A.** That is correct, the half a dozen or more
2 are animal model papers, yes.

3 **Q.** Chimpanzees, rabbits, any specific
4 species, monkeys?

5 **A.** No. They are upper level primates.

6 **Q.** In the hierarchy of evidence, where do
7 animal studies fit in compared to prospective
8 randomized control trials in women or prospective
9 observational cohorts or retrospective or prospective
10 epidemiologic observational studies or case series in
11 women?

12 **A.** If you are looking at a risk and you are
13 trying to answer what is the mechanism behind the
14 risk, then using an animal model is the most
15 appropriate way to find that.

16 **Q.** There can be differences in findings for
17 animals across the species, correct?

18 **A.** Yes, but the use of an upper level primate
19 would be the closest to looking at the basic science
20 in a female.

21 **Q.** What is the basis for that statement?

22 **A.** It's -- they are the closest species to us
23 as far as our genetic makeup, our bipedal mobility, so
24 that if you are -- you know, if you are going to use

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1 an animal model, using an upper level primate would be
2 the closest model that we have to using it in humans.

3 Q. You mentioned other studies utilizing the
4 lighter weight, larger pore mesh. I take it you were
5 referring to prolapse or hernia studies?

6 A. Well, all of the slings that --
7 midurethral slings that are currently on the market,
8 just like the SPARC that we were talking about before,
9 SPARC just like the TVT retropubic is a heavy weight,
10 small pore stiff mesh. So, therefore, because there
11 is a slight difference in the erosion rate between
12 SPARC and TVT, it is still a heavy weight, stiff,
13 small-pore mesh just like the TVT and, therefore, will
14 have the same defect of a heavy weight, small pore,
15 stiff mesh as the TVT.

16 Q. Now, I thought you have testified under
17 oath before that the laser cut form of cutting the TVT
18 mesh leads to a stiffer mesh?

19 A. No. It in- -- well, it does increase the
20 stiffness of an already stiff heavyweight mesh.

21 Q. And you've also testified that a laser cut
22 TVT mesh has a higher risk of exposure, correct?

23 A. The laser cut TVT compared to the
24 mechanical cut TVT does have a higher rate of

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1 exposure.

2 Q. And you're familiar with prolapse studies
3 using Ultrapro mesh that found exposure rates of
4 upwards of 14 to 15 percent, correct?

5 A. When Ultrapro --

6 Q. That's a yes or no. Are you aware of
7 those studies or no?

8 MR. CARTMELL: Let him answer and then you
9 can --

10 MR. SNELL: No, no, no. I'm going to ask
11 because this is going to the judge.

12 BY MR. SNELL:

13 Q. I'm going to ask you for a yes or no and
14 then you can explain all you want to. I'm just
15 saying, you're aware?

16 A. I'm aware of a Milani study that showed a
17 10 percent risk of erosion with Ultrapro.

18 Q. Are you aware that when they reported the
19 median term outcomes that the rate of exposure was
20 greater than 14 percent in that same cohort using
21 Ultrapro for a different application?

22 A. That is correct.

23 Q. Okay.

24 A. However, when head-to-head Ultrapro with

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1 GYNEMESH PS, there were half of the erosions with
2 Ultrapro.

3 MR. SNELL: Let's take a break. I think we are
4 moving things along here.

5 (WHEREUPON, a recess was had
6 from 3:15 to 3:33 p.m.)

7 BY THE WITNESS:

8 A. Before we get started, I think I might not
9 have completely understood your question about the
10 design and, you know, obviously what I would design
11 out are the things that I've outlined in my report,
12 the roping, fraying, curling, degradation, contraction
13 of the mesh.

14 Now, obviously the best way to do that is
15 with the alternatives that I've been describing, the
16 Burch procedure, the pubovaginal sling procedure. If
17 it was a -- I mean, I used Ultrapro as an example
18 since that is an example that is on the market.
19 Obviously in order to justify the use of a
20 polypropylene-based product like Ultrapro, there would
21 have to be a significant amount of research to be able
22 to make sure that the amount of polypropylene that's
23 leftover in Ultrapro, it is large -- a lighter weight,
24 larger pore, smaller filament size is "biocompatible"

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1 with tissue.

2 If you look at a single suture of
3 polypropylene, that is probably below the minimal
4 amount of polypropylene that is biocompatible with the
5 body, just like when you look at flu vaccines, a flu
6 vaccine has heavy metals in it, such as mercury and
7 others. There is a minimal amount of -- of things
8 like heavy metals and other toxic substances that is
9 still biocompatible, even though at higher levels it
10 becomes bioincompatible.

11 And, so, therefore, there would need to be
12 a significant amount of research to look at the --
13 whether the amount of polypropylene in Ultrapro is
14 still at the level of biocompatibility. The research
15 does seem to show that it is, as we've talked about
16 before in other depositions, but that would also need
17 to have, you know, a significant amount of research to
18 be able to say if that is the case.

19 BY MR. SNELL:

20 Q. Well, you and I both know from looking at
21 the literature that there can be exposures and
22 dyspareunia with the Ultrapro mesh followed in women
23 implanted with that mesh for pelvic floor indications,
24 specifically pelvic organ prolapse, right?

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1 **A.** That is correct.

2 **Q.** And what is the minimum amount of prolene
3 polypropylene that is biocompatible?

4 **A.** Well, again, we know that heavyweight,
5 small pore, large filament mesh that curls, degrades,
6 ropes, frays is not biocompatible. A single suture of
7 polypropylene is biocompatible. So there is in
8 between that a level of polypropylene that would be
9 minimal enough to be biocompatible.

10 **Q.** So my question is:

11 What is the minimal amount of prolene
12 polypropylene that is biocompatible? And if you know
13 that, what is the methodology by which you have -- you
14 can identify for me that minimum amount?

15 **A.** Well, the methodology would be the
16 risk/benefit analysis that shows the least amount of
17 risk for the benefit. From what I see with Ultrapro,
18 the studies that look at the stiffness of Ultrapro,
19 that look at the percentage of complications being
20 half of that of the next category of weight would show
21 me that Ultrapro comports with that biocompatibility.

22 **Q.** So the Ultrapro mesh regardless of its
23 size to you is biocompatible, correct?

24 **A.** The -- irregardless of the size?

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1 Q. Yes.

2 A. Of the amount of mesh?

3 Q. Yes.

4 MR. CARTMELL: Objection.

5 BY THE WITNESS:

6 A. Well, we are talking about using it as a
7 sling.

8 BY MR. SNELL:

9 Q. No, no, no. My question was:
10 What is the minimum amount of prolene
11 polypropylene that is biocompatible?

12 A. As a sling.

13 Q. No, no.

14 I want to know what's the minimum amount
15 of prolene polypropylene that is biocompatible in the
16 body?

17 MR. CARTMELL: Well, he is testifying about
18 slings.

19 MR. SNELL: Hold on. Don't do a speaking
20 objection.

21 BY MR. SNELL:

22 Q. Because I'm asking that because you said
23 two things. You said we have essentially two ends of
24 the spectrum. A single polypropylene suture, yes, I

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1 believe that's biocompatible. The mesh, and you keep
2 talking about heavyweight, large pore, small pore
3 mesh, no, that's not. I want to know where is it
4 that -- what is the minimum amount of prolene
5 polypropylene that is biocompatible?

6 **A.** For a sling?

7 **Q.** No. This is in the body in general
8 because you've now raised two different spectrum.
9 Because the sling doesn't use the prolene suture by
10 itself, right?

11 **A.** That is correct. You have a --

12 **Q.** And then for the other end --

13 **A.** -- you have hundreds of yards of
14 polypropylene.

15 **Q.** The other end of the spectrum, you were
16 referring to prolapse or hernia mesh or some other
17 application, right?

18 **A.** I was looking at that as a sling
19 application.

20 **Q.** Okay. Fine.

21 So between the spectrum then, can you tell
22 me, what is the minimum amount of prolene
23 polypropylene that's biocompatible?

24 **A.** Somewhere at the level of Ultrapro or less

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1 as a sling.

2 Q. And so what clinical studies in women
3 allow you to make that statement for the application
4 of stress incontinence besides the Okulu that we've
5 already talked about?

6 A. And all of the other research about
7 Ultrapro as a -- being implanted in both the female
8 pelvis and in animal models.

9 Q. There is no randomized control trials
10 comparing TVT to Ultrapro in the application of TVT's
11 treatment of stress incontinence, right?

12 A. That is correct.

13 Q. You've never used Ultrapro as a sling to
14 treat stress incontinence?

15 A. That is correct.

16 Q. There are no long-term studies utilizing
17 Ultrapro in women to treat stress urinary
18 incontinence, correct?

19 A. Long-term, the Okulu study I think it was
20 three years.

21 Q. So I would be correct that there are no
22 long-term studies utilizing Ultrapro in the treatment
23 of stress urinary incontinence, correct?

24 A. That is correct.

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1 you testified actually to a California jury that a
2 stiffer laser cut mesh can lead to more retention.

3 Do you recall that?

4 **A.** If that's what I stated, yes.

5 **Q.** That's an opinion you hold, correct?

6 **A.** If that's what I stated, yes.

7 **Q.** Can you say to a reasonable degree of
8 medical certainty that laser cut mesh is safer than
9 mechanically cut for the application of stress urinary
10 incontinence treatment?

11 **A.** Mechanical cut mesh ropes, frays, curls,
12 has particle loss associated with it. It twists. It
13 has sharp edges. Laser cut mesh is stiffer than
14 mechanical cut mesh but it also contracts, degrades,
15 undergoes a chronic foreign body reaction, chronic
16 inflammation. They both have different harms that are
17 caused by the cutting process.

18 MR. SNELL: I'm going to have to move to strike.

19 Can you read back my question?

20 BY MR. SNELL:

21 **Q.** And if you can answer it yes or no and
22 then explain.

23 (WHEREUPON, the record was read
24 by the reporter as requested.)

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1 BY THE WITNESS:

2 A. It is safer because it does not rope,
3 fray, curl and have particle loss.

4 BY MR. SNELL:

5 Q. And what's your methodology for that
6 statement?

7 A. The methodology for that statement is my
8 clinical experience with mechanical cut mesh, the
9 materials that I've reviewed in this litigation,
10 internal documents, the documents that discuss the
11 decrease in the roping, fraying, curling associated
12 with laser cut mesh that was documented in the
13 internal documents that I reviewed.

14 Q. What clinical studies in women for the
15 application of stress urinary incontinence show that
16 laser cut mesh is safer than mechanically cut mesh?

17 A. As far as roping, fraying, curling?

18 Q. So maybe my question wasn't clear.

19 What clinical studies in women for the
20 application of stress urinary incontinence show that
21 the laser cut mesh is safer than the mechanically cut
22 mesh in TVT?

23 A. As it relates to roping, fraying, curling
24 and particle loss?

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1 Q. At all. Because roping, fraying, curling,
2 particle loss are not complications, are they?

3 A. No. They cause erosion, pain and
4 dyspareunia.

5 Q. Right. And you already told me before
6 laser cut mesh has a higher risk of erosion than
7 mechanical cut mesh, right?

8 A. Because it is stiffer, yes.

9 Q. Right. So that leaves pain and
10 dyspareunia, correct?

11 MR. CARTMELL: Object to form.

12 BY THE WITNESS:

13 A. Well, mechanical cut mesh causes erosion
14 for a different reason than laser cut mesh.

15 BY MR. SNELL:

16 Q. Right. So what studies in women show that
17 the mechanical cut mesh has a higher rate of erosion
18 than the laser cut?

19 A. When laser cut is compared to the
20 mechanical cut mesh in the Hinoul, H-i-n-o-u-l, TVT
21 study, there was a higher rate of erosion than the
22 laser cut mesh.

23 Q. So my question was:
24 What studies in women for the stress

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1 incontinence application showed that mechanically cut
2 mesh leads to more erosions than laser cut mesh?

3 **A.** The only study that directly compared
4 laser cut mesh with mechanical cut mesh showed a
5 higher rate of erosion in the laser cut mesh.

6 **Q.** Okay. What clinical studies in women for
7 the application of stress incontinence show a
8 statistically significant higher rate of pain seen
9 with the mechanically cut mesh compared to the laser
10 cut TVT mesh?

11 MR. CARTMELL: Can you restate that? I
12 apologize.

13 MR. SNELL: I'm going to have her read it back
14 because I think it's a good question.

15 (WHEREUPON, the record was read
16 by the reporter as requested.)

17 BY THE WITNESS:

18 **A.** Besides the one study that I referenced,
19 there are no known direct comparisons between laser
20 cut mesh and mechanical cut mesh that looks at safety
21 outcomes.

22 BY MR. SNELL:

23 **Q.** What one study are you referencing?

24 **A.** The Hinoul study in the Journal of

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1 Urology.

2 Q. The Hinoul study did not show mechanically
3 cut TVT mesh had a higher rate of pain than the laser
4 cut mesh, correct?

5 A. Well, you were looking at an obturator
6 sling versus a mini-sling, and so there would be --
7 there was higher pain associated with the obturator
8 sling, which was the mechanical cut mesh.

9 Q. Let me restate.

10 The Hinoul study that you referenced as
11 the only study that you are aware of is a
12 transobturator versus TVT-Secur mini-sling randomized
13 trial, right?

14 A. That is correct.

15 Q. Okay. So for the application of the TVT
16 retropubic device, am I correct that you are not aware
17 of any randomized control trials in women looking at
18 stress urinary incontinence that show a statistically
19 significant higher rate of pain for the mechanically
20 cut TVT compared to a laser cut TVT?

21 A. That is correct, and the reason for that
22 is it was not studied in women. Doctors were told
23 that mechanical cut mesh and laser cut mesh were the
24 same. There were no clinical studies to show whether

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1 or not mechanical cut mesh versus laser cut mesh was
2 safer in a randomized control trial.

3 Q. Have you seen in any of the professional
4 organization statements and guidelines and
5 meta-analyses that they have reported that mechanical
6 cut TVT mesh has statistically significant higher
7 rates of pain than the laser cut TVT mesh?

8 A. As we know from the internal documents,
9 most doctors don't know whether they are getting
10 mechanical cut mesh or laser cut mesh. Most doctors
11 don't even know that there is a difference between
12 mechanical -- that there is a mechanical cut mesh
13 versus laser cut mesh.

14 MR. SNELL: Move to strike his answer to my
15 question.

16 BY MR. SNELL:

17 Q. Is the answer to my question no?

18 MR. CARTMELL: What was your question again?

19 MR. SNELL: You have to read it back. I'm
20 sorry, Madam Court Reporter.

21 (WHEREUPON, the record was read
22 by the reporter as requested.)

23 MR. CARTMELL: Object to the form. I think you
24 are insinuating that's in the statements and that's

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1 nowhere to be found in any statement.

2 BY MR. SNELL:

3 Q. My question is:

4 Have you seen that, whether that's in
5 those statements?

6 A. No, for the reason that I have stated.

7 Q. Are you aware of any randomized control
8 trials in women that report that the mechanically cut
9 TVT retropubic mesh has a statistically significant
10 higher rate of dyspareunia compared to laser cut TVT
11 retropubic mesh?

12 A. No, for the reasons that I stated earlier.

13 Q. Are you aware of any clinical studies
14 suggesting an increase rate of pain with sex
15 attributable to laser cut mesh?

16 A. Yes.

17 Q. Which studies are those?

18 A. Those are the Neumann studies.

19 Q. What does that study report with regard to
20 the laser cut mesh?

21 A. It's a TVT-Secur, TVT-Obturator study that
22 showed 9 percent dyspareunia with laser cut mesh.
23 Secur compared to the TVT and the Neumann states that
24 the laser cutting leading to stiffness of the mesh

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1 degradation of the mesh.

2 My question to you is:

3 Have any of those complications been
4 reported to be due to degradation in any prospective
5 study in women undergoing treatment for stress urinary
6 incontinence?

7 A. Have the studies on treatment for
8 complications of stress urinary incontinence stated
9 that there is degradation of the -- of the mesh?

10 Q. I think you are changing my question
11 around.

12 A. Well, I was asking for clarification --

13 Q. Okay. Fair enough.

14 A. -- because I didn't understand it.

15 Q. That's fair.

16 A. Which is why when I repeated it back it
17 became even more convoluted, so.

18 Q. You threw me off there. Let me see if I
19 can rephrase it. Thank you for that.

20 So you've testified, and I'm not going to
21 rehash it, that you believe that degradation can lead
22 to certain complications. I think one of them is
23 erosion or exposure.

24 My question is this:

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1 Are you relying on any prospective studies
2 in women undergoing TVT implantation for stress
3 incontinence that report that the complication was due
4 to degradation of the mesh?

5 **A.** Wang 2004.

6 **Q.** Say it again?

7 **A.** Wang 2004, American Journal of Obstetrics
8 and Gynecology. Recurrent erosions were associated
9 with mesh degradation, fragmentation of the mesh, and
10 Dr. Wang concluded that this needed to be looked at on
11 a prospective basis.

12 **Q.** And was Wang 2004 reported or cited in
13 your --

14 MR. CARTMELL: Yes, and you've gone through it
15 with him before in prior depositions.

16 BY THE WITNESS:

17 **A.** Yes, we have gone through this before in
18 prior depositions.

19 BY MR. SNELL:

20 **Q.** So this is the only study you can cite to
21 for the proposition that in women with clinical
22 follow-up with TVT used for the application of stress
23 incontinence that degradation leads to complications?

24 **A.** You said prospectively. This was a

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1 prospective study, yes.

2 Q. Okay. Correct me if I'm wrong, but in
3 that study they did not do a multivariate analysis of
4 patient factors and surgeon factors in the assessment
5 of which factors after assessment were statistically
6 significantly associated with the 2.4 percent rate of
7 defective vaginal healing?

8 MR. CARTMELL: I'm going to give you a little
9 bit of leeway here, that question, but you have gone
10 through this study more than once with this doctor.
11 Judge Eifert has been very clear that you are not
12 supposed to be duplicative in your questioning of
13 these experts. You've done it a bunch already today,
14 so I'm shutting it down after that question.

15 BY THE WITNESS:

16 A. May I see the study to see if that is
17 specifically described?

18 BY MR. SNELL:

19 Q. Sure.

20 (WHEREUPON, a certain document was
21 marked Rosenzweig Deposition Exhibit
22 No. 14, for identification, as of
23 09/22/2015.)

24 BY THE WITNESS:

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1 **A.** The answer to that question is no.

2 BY MR. SNELL:

3 **Q.** There was no --

4 **A.** But if I can explain, Dr. Wang, as we have
5 talked about before, was part of the initial 510(k)
6 submission, his data. He is one of the largest users
7 of slings. So I would doubt that surgeon factor would
8 be a significant cause of the erosions in this case.

9 **Q.** Well, mesh erosions can happen to
10 experienced skilled surgeons, certainly, right?

11 **A.** That is correct because of the
12 characteristics of the mesh.

13 **Q.** And his 2.4 percent rate is not outside of
14 the overall body of literature, correct?

15 **A.** This is the recurrent erosions, not the
16 simple-to-treat erosions.

17 MR. SNELL: Move to strike.

18 BY MR. SNELL:

19 **Q.** This 2.4 percent is not outside the
20 overall medical literature reporting on mesh
21 exposures, correct?

22 MR. CARTMELL: Objection; asked and answered.

23 BY THE WITNESS:

24 **A.** For recurrent erosions, no.

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1 BY MR. SNELL:

2 Q. And this study does not tell us what was
3 the percentage of degradation, if any, that occurred?

4 A. In the patients with defective healing,
5 the inflammatory process was accompanied by pronounced
6 peri-filamentous fibrosis and foreign body reaction.
7 The histology showed mesh filaments were fragmented
8 and surrounded by palisading histiocytes.

9 MR. SNELL: Objection; move to strike.

10 BY MR. SNELL:

11 Q. So this study does not tell us the
12 percentage of mesh degradation, correct?

13 A. It does not give a specific number, no.

14 Q. It does not tell us the total volume of
15 mesh degradation in this 2.4 percent of women,
16 correct?

17 A. Correct.

18 Q. It does not compare and tell us what the
19 histologic findings were in the 700-plus women who did
20 not a mesh exposure, did it?

21 A. The histologic findings?

22 Q. Yes.

23 A. No.

24 Q. Because you don't do histologic findings

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1 in women who don't have exposure and don't have
2 complications, do you?

3 A. We reviewed a paper earlier that did, but
4 in the majority of cases, no.

5 Q. Are there any clinical studies assessing
6 TVT in women with stress urinary incontinence that
7 reports that cytotoxicity of the mesh is a cause of
8 their -- any reported complications?

9 A. Erosion is a sign of cytotoxicity.

10 MR. SNELL: Move to strike.

11 BY MR. SNELL:

12 Q. You are telling me stuff I already know
13 you've told me before. I'm trying to be respectful
14 with Tom over hear screaming at me.

15 MR. CARTMELL: You've asked that question you
16 just asked too.

17 MR. SNELL: I haven't asked that question.

18 MR. CARTMELL: Yes, you have.

19 MR. SNELL: Read back my question, please.

20 (WHEREUPON, the record was read
21 by the reporter as requested.)

22 MR. CARTMELL: Objection; asked and answered.
23 If you need to tell him again, tell him again.

24 BY THE WITNESS:

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1 **A.** Erosion is a sign of cytotoxicity.

2 MR. SNELL: I'll move to strike again.

3 BY MR. SNELL:

4 **Q.** I'm asking you for clinical studies, all
5 right. Are there clinical studies -- I'm not asking
6 you what your opinion is about whether erosion is a
7 sign of cytotoxicity or not.

8 So can you not --

9 MR. SNELL: Can you reread my question one more
10 time.

11 (WHEREUPON, the record was read
12 by the reporter as requested.)

13 BY THE WITNESS:

14 **A.** No.

15 BY MR. SNELL:

16 **Q.** You earlier stated that erosion is a sign
17 of cytotoxicity in your opinion. Just so I'm clear,
18 were you referring to mesh exposure or the erosion of
19 the mesh into the bladder or urethra?

20 **A.** Either one. And the scientific studies
21 that show that are the Moalli papers on apoptosis and
22 cell death associated with heavyweight mesh.

23 **Q.** Those are not papers in women though,
24 right?

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1 **A.** That is correct.

2 **Q.** I'm trying to think of a way to ask this
3 question.

4 If a woman -- if a woman has a mesh
5 erosion or mesh exposure -- strike that.

6 Let's say there was a study and an
7 analysis done and it reported a 2.2 percent rate of
8 vaginal mesh exposure, okay.

9 You are with me so far?

10 **A.** Yes, sir.

11 **Q.** And numbers similar to that that
12 Dr. Blaivas reported in Table 3 of his 2015 review
13 article for retropubic slings, okay?

14 **A.** Which is probably an underestimate of the
15 total number of erosions, but go ahead.

16 **Q.** So if we extrapolate that out, let's say
17 that will be 22 women out of 1,000 women, correct?

18 **A.** That have been followed up to find their
19 erosion, yes.

20 **Q.** So here is my question. So if we take
21 those 22 women, is there a scientifically reliable
22 study or studies in women who have received the mesh
23 that would allow one to say which of those 22 women
24 had the erosion or exposure because of cytotoxicity or

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1 was it due to some other reason?

2 Do you understand my question?

3 A. Yes. It could be due to degradation, it
4 could be due to mesh contraction, chronic foreign body
5 reaction, chronic inflammation or cytotoxicity. For
6 me to sit around and say what percentage would be
7 cytotoxicity, what percentage would be degradation,
8 that is impossible to do. We know all of those
9 mechanisms can lead to mesh erosion or mesh exposure,
10 however we want to describe that.

11 Q. But as you sit here, you can't say which
12 of those particular mechanisms, you call it
13 degradation, contraction, inflammation, cytotoxicity,
14 produce an exposure in a particular woman?

15 MR. CARTMELL: Object to the form.

16 BY THE WITNESS:

17 A. Also I would add roping and fraying along
18 with that.

19 BY MR. SNELL:

20 Q. So roping and fraying. You can't say for
21 all of those mechanisms which one leads to a mesh
22 exposure in a particular woman, correct?

23 MR. CARTMELL: Object. Are you asking -- for
24 clarification, are you asking about in a study or are

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1 you asking about --

2 MR. SNELL: You are giving a speaking objection,
3 Tom. Knock it off.

4 MR. CARTMELL: No. I need to know what you are
5 talking about.

6 MR. SNELL: Knock it off.

7 MR. CARTMELL: It makes no sense. You were
8 talking about a study, you were saying hypothetically
9 there is 2.2 percent rate. If you are asking him in a
10 particular patient that's in front of him or he's
11 treating, can he figure that out, or are you asking
12 him in a study by looking at a paper? That's what --
13 it's vague and ambiguous, it lacks foundation, it
14 calls for speculation until you tell him that.

15 BY MR. SNELL:

16 Q. You have identified different potential
17 mechanisms by which you believe exposures can occur,
18 namely, degradation, contraction, chronic
19 inflammation, cytotoxicity, roping and curling?

20 A. And fraying.

21 Q. And fraying. So we've got seven, right?

22 A. Yes.

23 Q. Can you say which of those mechanisms
24 caused an exposure in a particular woman?

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1 **A.** In a particular woman, no.

2 **Q.** Can you say which of those mechanisms
3 caused an exposure in a group of 20 women who had
4 exposures?

5 **A.** If I had the mesh under a microscope where
6 we could see that there was roping, fraying, curling,
7 particle loss, degradation, contraction and
8 deformation, then any one of those would have caused
9 that.

10 **Q.** So you would need the mesh to be assessed
11 under a microscope?

12 **A.** To know the exact mechanism, it would be
13 very helpful to see what the microscopic findings
14 were.

15 **Q.** Because -- and are you saying a scanning
16 electron microscope or just the regular pathology
17 microscope?

18 **A.** The SEM would be able to tell you if there
19 is degradation. The lower power microscope can show
20 you if there is roping, fraying, curling and
21 contraction of the mesh.

22 **Q.** Well, the SEM shows the surface
23 irregularities on the mesh, correct?

24 **A.** No. It shows breaking of the mesh,

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1 BY MR. SNELL:

2 Q. Have you analyzed the literature and seen
3 any studies or do you know of data that reports on the
4 percentage of surgeons in the urogynecology or
5 gynecology field who rely upon an Instructions for
6 Use?

7 A. Have I seen it published in a -- in an
8 article about the number of doctors that rely on
9 Instructions for Use?

10 Q. Yes, the percentage of doctors, you know,
11 who rely or do not rely on the Instructions for Use?
12 And the reason I'm asking is you were involved in the
13 Lewis case, you know Dr. Boreham said, "I don't rely
14 on the IFU," right?

15 MR. CARTMELL: Object to the form.

16 BY THE WITNESS:

17 A. If I recall, that's what she testified to.

18 BY MR. SNELL:

19 Q. Okay. Fair enough. So that's where my
20 question is coming from.

21 Have you seen actually any, you know,
22 data, any literature that's been peer reviewed or any
23 surveys put out by AUGS, AUA, SUFU or anybody else who
24 you would recognize as having an authoritative voice

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1 in the field of female pelvic medicine who have
2 presented that data that says, Okay, this is the
3 percentage of surgeons doing TVT retropubic or
4 synthetic midurethral slings who rely on IFUs?

5 A. I don't think that study has been done.

6 Q. And have you seen or are you aware of any
7 similar studies that report on how surgeons interpret
8 the adequacy of IFUs for stress incontinence devices?

9 A. I have not seen any studies like that.

10 MR. SNELL: Okay. That's all I have. Thank
11 you.

12 EXAMINATION

13 BY MR. CARTMELL:

14 Q. I have a few follow-ups, Doctor.

15 You were just asked about your opinion
16 that's in your report related to tensioning of the
17 device.

18 Do you recall that?

19 A. Yes.

20 Q. Now, your opinion in this case, and it's
21 in your report, is that the TVT retropubic at issue in
22 this case is defective, correct?

23 MR. SNELL: Objection; leading.

24 BY THE WITNESS:

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1 know, don't speculate.

2 BY THE WITNESS:

3 A. I will not speculate on all of the other
4 IFUs.

5 BY MR. SNELL:

6 Q. You don't know as you sit here today,
7 correct?

8 A. I know about the ones that I've described
9 before.

10 Q. Can you just answer my question yes or no?
11 I'm literally looking for an honest answer. Can you
12 as you sit here today tell me that other
13 manufacturers' stress incontinence IFUs report
14 frequency, severity, treatability and longevity for
15 complications associated with their stress
16 incontinence devices, yes or no? That's all I want no
17 know.

18 A. Each individual complication?

19 Q. Yes, sir.

20 A. The ones I have seen, no.

21 MR. CARTMELL: You are now going beyond the
22 scope of my cross with questions like that which is
23 not allowed, so I'm about to shut you down.

24 MR. SNELL: No, no. He went into frequency,